## IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re the Application of

Inventor: Yi Mei Hsieh CHEN Art Unit 3762

Appln. No.: 10/699,659 Exr. C. Flory

Filed: November 4, 2003 Conf. No. 3762

For: MODULAR STRUCTURE FOR HEART BEAT SIGNAL WIRELESS

TRANSMITTER

## RESPONSE UNDER 37 CFR § 1.111

Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450

Sir:

In response to the office action dated June 2, 2007, the Applicant hereby reconsideration and allowance of this application in light of the following remarks.

The Applicant acknowledges with appreciation the indication that the rejections under 35 USC 112, first and second paragraphs, have been withdrawn.

Claims 1-22 stand rejected, under 35 USC §102(b), as being unpatentable over Nissila (US 2002/0068873). Claims 21 and 22 stand rejected under 35 USC 102(b) as anticipated by newly applied Allison (USPN 4,016,868). Claims 21 and 22 stand rejected under 35 USC 102(b) as anticipated by newly applied De La Huerga (USPN 6,346,886). Claims 1-16, 19, 20 and 22 stand rejected under 35 USC

102(b) as anticipated by Sackner et al. (USPN 6,551,252). Claims 1-20 and 22 stand rejected under 35 USC 103(a) as obvious over Sackner et al. (USPN 6,551,252) in view of Nissila (US 2002/0068873). The Applicant respectfully traverses based on the points set forth hereinbelow.

As noted in the previous Response, Sackner fails to disclose the features recited in claims 21 and 22 of:

- (1) attaching an electronic wireless transmitter to electrically conductive fabric straps sewn into a washable garment of clothing so as to create electrical contact between the skin of the person wearing the garment and the fabric strips and thereby complete an electrical circuit for the transmitter through the person's skin that provides heart beat signals to the transmitter and
- (2) detaching the transmitter from the fabric straps so that the garment may be washed without damaging the transmitter.

The office action proposes at page 7 that Sackner's electronic sensors 42-44 are inherently removably attachable to electrodes 10 and 11 and thus the garment is washable.

As further noted in the previous Responses, the subject matter of claims 1-20 similarly provides the advantages described above in connection with claim 21. As noted previously, the claimed invention is directed to a heart beat signal wireless transmitter

which comprises a watch-like body and a pair of detachable fastening belts that are capable of being separated from and connected to the body, and this structure permits the body to be constructed of at least four different modularized structures, and each modularized body can be assembled and sued together with the same pair of detachable fastening belts to form a heart beat signal wireless transmitter. Sackner discloses a monitoring garment comprising a shirt for the torso of an individual. The shirt comprises a plurality of inductive plethysmographic (IP) sensors particularly "as an integral part of the garment", and each IP sensor includes at least one flexible conductive loop arranged for close encirclement of the individual's torso. In addition, Sackner discloses a microprocessor unit for receiving the signals transmitted from the IP sensors.

In contrast to the claimed invention, Sackner fails to disclose or suggest a pair of detachable fastening belts that are separable from the body. Sackner also fails to disclose or suggest that their device can be fixed on an individual's undergarment, which would provide more comfort then wearing a special shirt designed with a tight encirclement of sensors that is disclosed by Sackner.

In addition, Sackner fails to disclose or suggest the presently claimed a PC board carrying a signal transmitter inside,

and a clamping means provided on the two sides of the body. Nor does Sackner disclose or suggest the presently claimed clamping means grips or releases the front part of a corresponding detachable fastening belt, and when gripping the corresponding detachable fastening belt forms an electrical connection. This clamping means provides the claimed invention with a structure that permits the fastening belts to be separated from the body and convertibly connected to a different or another type of modularized body, for example, when the body needs repair, or the cardiologist determines that a different type of monitoring body should be used for a certain patient.

In addition, Sackner also fails to disclose or suggest a pair of detachable fastening belts made of a fabric material having a waterproof property of which the front part is made of a conductive fabric and formed in electrical connection with the PC board inside the body, after the pair of fastening belts has been connected to the two sides of the body separately by the clamping means. In other words, each one of the pair of detachable fastening belts respectively function as a positive electrode or a negative electrode to the PC board so as to enable a precise detection of the heartbeat signal by having the conductive fabric of each detachable fastening belt be arranged in close contact with the user's skin.

In addition, the fastening belts in the presently claimed invention may also have a nonconductive that permits attachment to an undergarment through the clamping means. This structure, which is not disclosed or suggest by Sackner, provides the advantage of being removable to allow the garment to be washed for reuse after separating the fastening belts from the undergarment.

In contrast, the IP sensors in Sackner are an integral part of the garment, meaning that the shirt of the Sackner patent cannot be washed for reuse. Sackner discloses sensor band using an elastic material that is not used as a conductive or non-conductive fabric of an electrode.

Moreover, Sackner shows a tightening device (8) in Fig. 1 and Velcro strips (32) in Fig. 2 and 3 which are a different structure than the claimed detachable fastening belts, and do not function as an electrode. The only purpose of the tightening device and Velcro strips is to be snugly fastened on to the user's body via the tightening device (8) or Velcro strips (32). Thus, Sackner fails to disclose the detachable fastening belts having the structure and function as in the presently claimed invention.

The Applicant further notes that the so-called "Inductive plethysmography", referred to in column 11, lines 25-67 and column 12, lines 1-20 of the specification of Sackner, refers to measurement of a cross-sectional area of an individual body by

determining the changes in inductance varied from a flexible conductor, if being "closely looped around" the cross-sectional area of the body to be measured, having the property of the loop inductance of the looped flexible conductor varying with the cross-sectional area encircled by the looped flexible conductor being changed. The so-called "Inductive plethysmography" is applicable to measure various physiological parameters of medical and research interest by repetitively measuring of the areas of various cross-sections of an individual body.

Accordingly, the following physiological parameters may be determined by the so-called "Inductive plethysmography":

- a) pulmonary function parameters, such as respiration volumes and rates and apneas and their types, may be determined from measurements of a chest transverse cross-sectional area and/or an abdominal transverse cross-sectional area; and
- b) cardiac parameters, such central venous pressure, left and right ventricular volumes waveforms, and aortic and carotid artery pressure waveforms, may be extracted from repetitive measurement of transverse cross-sectional areas of the neck and of the chest passing through the heart.

The basic structure of a conventional wireless heartbeat transmitter, for easy understanding by taking U.S. Pat. No. 5,464,021 (hereinafter Birnbaum '021) as an illustrative example,

includes a pair of conductible rubbers (5) used as an electrode for monitoring heartbeat signal and a circuit board (6) with a signal transmitter, and, as shown in FIG. 4 of Birnbaum '021, while the wireless heartbeat transmitter (1) is fastened to a carrying belt (11) and tightened around the chest of a user, the conductible rubber (5) and the circuit board (6) form an electrical connection, and then the heartbeat signal of the user is monitored by the conductible rubber (5) and wirelessly transmitted from the signal transmitter of the circuit board (6) to a separate but corresponding receiver to reach a goal of wirelessly monitoring an user's heartbeat.

Due to no cross-sectional area being varied while a heartbeat signal to be measured, it is quite apparent that the heart beat signal is not measured by the so-called "Inductive plethysmography." In other words, it is meant the wireless heartbeat transmitter of the present claimed invention is provided with conductible fabric used as an electrode, not provided with the so-called "Inductive plethysmography."

The practicable field of the present invention is independent and different from those of the prior art cited by the office action, specially, Sackner.

The present invention provides a modular structure for heartbeat signal wireless transmitter which practical field is

adapted for monitoring a user's heart rate in sports/athletics training and in fitness training.

By contrast, Sackner relates to the field of ambulatory and non-invasive monitoring of an individual patient's <u>pulmonary and cardiac parameters</u> for home-based self health care during the patient's normal daily activities (see, col. 5 lines 15-31 and Figure 9), <u>not for monitoring a user's heart rate in sports/athletics training and in fitness training</u>.

A key feature of the present invention is disclosed to use conductive fabric as an electrode, which function is also designed to be detachable to mate with four different modularized bodies for monitoring heartbeat signal.

Particularly, a pair of detachable electrodes made of conductive fabrics may be fixed on any underwear or any bra by sewing to constitute a kind of exposed electrode. The underwear or the bra may be still worn as a clothing object with a washable function, if no modularized body (30) is coupled to the pair of detachable electrodes made of conductive fabrics, but, the underwear or the bra is further adapted for monitoring a user's heart rate in sports/athletics training and in fitness training, while any one of modularized bodies (30) is coupled to the pair of detachable electrodes of the underwear or the bra.

Accordingly, the structure of the invented heart beat signal wireless transmitter of the present invention, is a heart beat signal detector which comprises a watch-like body and a pair of detachable fastening belts made of conductive fabrics capable of being separated from and connected to the watch-like body, so that the watch-like body can be especially constructed as four different modularized structures and each modularized watch-like body could be assembled and used together with the same pair of detachable fastening belts to form a heart beat signal wireless transmitter.

The basic structure of a monitoring apparatus for non-invasively monitoring physiological parameters of an individual of Sackner at least comprises a monitoring garment (or torso) 1 worn on the individual to be monitored, one or more inductive plethysmographic (IP) sensors, a cardiac cycle sensor, a signal cable for carrying signals from the sensors and a microprocessor unit for receiving signals from the signal cable and for recording digital data derived from all received signals in a removable computer-readable memory media.

Particularly, each IP sensor comprises an inductance sensor including at least one conductive loop arranged to closely encircle the garment (or torso) 1, wherein the inductance of the conductive loop is responsive to the cross-sectional area of the garment (or torso) 1 enclosed by the loop, and the IP sensors are made of

sinusoidally arranged copper wire and attached to the garment (or torso) 1 as an integral part of the garment via an attachment consisting of one of sewing, embroidering, embedding, weaving and printing the inductive plethysmographic sensor into the garment (or torso) 1.

Also, the cardiac cycle sensor for generating signals responsive to occurrence of cardiac ventricular contractions. Referring to column 13, lines 49-67 and column 14, lines 29-58 of Sackner, to measure basic pulmonary parameters, the garment 1 of Sackner is equipped with a chest inductive plethysmographic sensor band 4 (having loop-encircled flexible conductor) and abdominal inductive plethysmographic sensor band 6 (having loop-encircled flexible conductor).

To measure basic cardiac parameters, garment 1 of Sackner is equipped with thoracic inductive plethysmographic sensor band 5 (having loop-encircled flexible conductor) and optional neck inductive plethysmographic sensor band 7 (having loop-encircled flexible conductor), which is separate from garment 1.

Further, for measuring any ECG signals, the garment 1 of Sackner'252 is equipped with two cutouts 12 for attaching ECG electrodes and ECG leads 10 and 11.

By contrast to Sackner, it is apparent that <u>each IP sensor</u>, including the chest inductive plethysmographic sensor band 4, the

abdominal inductive plethysmographic sensor band 6, the thoracic inductive plethysmographic sensor band 5 and optional neck inductive plethysmographic sensor band 7 of the garment 1 of Sackner, are made of sinusoidally arranged copper wire and "closely looped around" the cross-sectional area of the garment (or torso) 1 and are not used to measure a heart beat signal from an individual.

And, two cutouts 12 for attaching ECG electrodes and <u>ECG leads</u>

10 and 11 of Sackner are not made of conductive fabric.

As a result, Sackner does not impliedly or explicitly disclose a heart beat signal wireless transmitter having a pair of detachable fastening belts made of conductive fabrics capable of being separated from and connected to a modularized watch-like body, and the present invention does not include a monitoring garment having a torso integrated with IP sensors provided with at least one flexible conductive loop arranged to closely encircle the torso.

It is apparent that the structure of the heart beat signal wireless transmitter disclosed in the present application is wholly different from that of a monitoring garment disclosed by Sackner.

The watch-like body of the present claimed invention includes four different modularized structures each having a PC board carrying a signal transmitter inside and a clamping means provided

on both sides of the body, with <u>each clamping means functioning to</u> grip or release the front part of a corresponding detachable fastening belt and make the gripped detachable fastening belt formed in electrical connection to the PC board so that each detachable fastening belt is capable of being separated from the watch-like body and convertibly connected to another modularized body to form a different kind of heart beat signal wireless transmitter.

By contrast, Sackner's <u>IP sensors and ECG electrodes and ECG</u>

<u>leads 10 and 11</u> are not separated from the garment (or torso) 1 and

formed as an integral part of the garment (or torso) 1.

As a result, Sackner'252 does not impliedly or explicitly disclose a heart beat signal wireless transmitter having a pair of detachable fastening belts made of conductive fabric capable of being separated from a modularized watch-like body and convertibly connected to another modularized watch-like body.

Each detachable fastening belt of the present application is made of fabric material with waterproof property which a front part is made of conductive fabric and formed in electrical connection with the PC board inside the watch-like body, after the pair of detachable fastening belts had been connected to both sides of the watch-like body separately through the clamping means of the watch-like body, the pair of detachable fastening belts

respectively function as a positive electrode and a negative electrode to PC board to enable a precise detecting of the heart beat signal of user by having the conductive fabric of each detachable fastening belt be contacted with the user's skin closely.

By contrast, no similar detachable fastening belt functioning as an electrode is disclosed on the monitoring garment of Sackner, in particular, both the disclosed tightening device (8) in Fig. 1 and the disclosed Velcro strips (32) in Fig. 2 or 3 of Sackner do not function as an electrode, but the garment (1 or 31) may be fastened snugly onto the body using tightening device (8) or Velcro strips 32.

As a result, Sackner does not impliedly or explicitly disclose a detachable fastening belt with conductive fabric formed at front end and capably functioned as an electrode. It is apparent that the structure and function of each detachable fastening belt of the present claimed invention is different from that of the tightening device (8) or the Velcro strips (32) disclosed by Sackner.

Due to each detachable fastening belt of the present invention being capable of being separated from the watch-like body and made of conductive fabric and non-conductive fabric with waterproof property, the non-conductive fabric of each fastening belt may be fixed on an underwear or a bra by sewing to keep the conductive fabric of each fastening belt exposed outside as an electrode.

The structure described above is constructed as another embodiment of a heart beat signal wireless transmitter of the present invention simply by installing a modularized body to the pair of detachable fastening belts having sewn on the underwear or bra through the clamping means of the watch-like body. And, the underwear or the bra carrying the detachable fastening belts can be washed for reuse after the watch-like body is separated from the fastening belt.

By contrast, no similar detachable fastening belt functioning as an electrode is disclosed on the monitoring garment of Sackner. In particular, due to <u>IP sensor bands</u> (4, 5 and 6) made of sinusoidally arranged copper wire and "closely looped around" the garment 1 and formed as an integral part of the garment and unable to be separated from the garment, the monitoring garment of Sackner can not be washed for reuse.

And, the disclosed IP sensor bands (4, 5 or 6) including an elastic material are mainly aimed at having the sensor bands (4, 5 or 6) of the monitoring garment of Sackner to be kept in close circumferential contact to the body, so that the elastic material used in sensor bands (4, 5 or 6) is not functioned as a conductive fabric or an electrode.

As a result, it is obvious the structure and function of each detachable fastening belt of the present claimed invention is different from that of the sensor bands (4, 5 or 6) having an elastic material disclosed on the cited Sackner'252.

Accordingly, based on the above-noted differences, the present claimed invention is hardly anticipated by Sackner, and is absolutely non-obvious to a person having ordinary skill in the art relating to the invented heart beat signal wireless transmitter.

Nissila '873 discloses a wrist-worn device (100) comprising a display 104 for showing the exercising variable value, a wire (110) and an electronics unit (108) all encapsulated in a wristband (102), i.e., the display (104) and the electronics unit (108) are sealed into the wristband (102) to enhance the waterproofness of the device because components sensitive to water are entirely surrounded by plastic.

As a result, it is apparent that the structure and function of a wrist-worn device (100) of Nissila '873 is not relevant to the structure of the invented heart beat signal wireless transmitter of the present invention.

Accordingly, the inventions of present claims 1-22 are not common knowledge to the ordinary person skilled in the art, and are patentable and allowable over Sackner alone or in view of Nissila '873.

Allison discloses a garment for impedance plethysmograph measurement of blood flow in an individual body.

As a result, due to Allison not relating to measuring a heart beat signal, it is apparent that the subject matter of claims 1-22 of the present invention is not the common knowledge to the ordinary person skilled in the art and is not disclosed by Allison.

De La Huerga discloses an identification bracelet which includes a plastic strap having first and second ends, an electronic memory device (e.g. a silicon chip), a securing means for securing the first and second ends together around a patient's wrist and a transponder. The memory device is integrally embedded in the strap and cannot be removed from the strap without destroying the device. The transponder includes circuitry which can receive information from and transmit information to remote hand held electronic devices or the like. The transponder is releasably attachable to the bracelet adjacent the memory device. When attached to the bracelet, the transponder makes contact with the memory device and can receive information from, and provide information to, the memory device.

De La Huerga does not relate to measuring a heart beat signal.

Thus, it is apparent that the subject matter of claims 1-22 of the

present invention is not the common knowledge to the ordinary person skilled in the art and is not disclosed by De La Huerga.

Nissila '943 provides an ECG electrode structure suitable for use in water during swimming and to a method for measuring an ECG signal from a person who is in water. But, Nissila'943 does not impliedly or explicitly disclose a heart beat signal wireless transmitter having a pair of detachable fastening belts made of conductive fabric capable of being separated from a modularized watch-like body and convertibly connected to another modularized watch-like body.

As a result, it is apparent that the subject matter of claims 1-22 of the present invention is not the common knowledge to the ordinary person skilled in the art and is not disclosed by Nissila '943.

Accordingly, based on the differences noted above, the present invention is in no way anticipated by Allison, De La Huerga or Nissila '943 and is absolutely non-obvious to a person having ordinary skill in the art related to the invented heart beat signal wireless transmitter.

In view of the above, it is submitted that claims 1-22 are not anticipated by any of the references of record, and are not rendered obvious by the individual or combined teachings of such references. Thus, this application is deemed to be in condition

for allowance and a notice to that effect is respectfully solicited.

If any issues remain which may best be resolved through a telephone communication, the Examiner is requested to telephone the undersigned at the local Washington, D.C. telephone number listed below.

Respectfully submitted,

Date: September 4, 2007

JEL/DWW/att

James E. Ledbetter

Registration No. 28,732

Attorney Docket No. <u>L9079.03107</u> STEVENS DAVIS, MILLER & MOSHER, L.L.P.

1615 L Street, N.W., Suite 850

P.O. Box 34387

Washington, D.C. 20043-4387

Telephone: (202) 785-0100 Facsimile: (202) 408-5200